

Remarks

I. Status of the Claims

Claims 1-4 are pending in the application. Claims 5-9 have been added. Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 2, and 4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,163,896 to Suthanthiran (hereinafter "Suthanthiran"). Claims 1-4 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,152,869 to Park (hereinafter "Park"), and separately, as being anticipated by U.S. Patent No. 5,871,436 to Eury (hereinafter "Eury"). Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Suthanthiran or Eury in view of either one of Park or U.S. Patent No. 5,342,283 to Good (hereinafter "Good").

Claims 1, 3 and 4 have been subject to a provisional rejection under 35 U.S.C. § 101 as claiming the same invention as that of Claims 1, 3, and 7 of copending Application No. 09/506,611 (double patenting). Claim 2 has been subject to a provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 09/506,611.

II. Double Patenting Rejections.

Claim 1 has been amended to include the subject matter of Claim 2. As Claim 2 has not been subject to a provisional rejection under 35 U.S.C. § 101, it is requested that the provisional rejection of Claims 1, 3 and 4 under 35 U.S.C. § 101 be withdrawn. A terminal disclaimer will be submitted if necessary.

III. Claim rejections under 35 U.S.C. § 112.

The Examiner has objected to the term "large area" in Claim 2. Claim 2 has been canceled and its subject matter incorporated into Claim 1, and the term "large area" has been deleted. Claim 1 now recites "rectangular and disc shaped sources configured to radiate an area." Applicant requests that the rejection under 35 U.S.C. § 112 be withdrawn.

IV. Claim rejections under 35 U.S.C. § 102.

Anticipation under 35 U.S.C § 102 requires that each and every element of the claim is found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Stated another way, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A 1978). "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

The present invention as recited by Claim 1 includes "an integral source material having at least one nuclide that is activatable by exposure to radiation, the nuclide is a chemically bound constituent of a polymer chain of the integral source material, wherein the integral source material is configured before activation to provide a device."

Applicant submits that none of the references cited in the Action provide a nuclide that is a chemically bound constituent of a polymer chain and activatable by exposure to radiation.

Eury discloses a stent for delivering a dosage of radiation to a localized site within a patient. The radiation dosage is controlled by immersing the device in a solution containing the appropriate radioactive material to absorb the radioisotope. Eury, col. 3, lines 16-18. More specifically, the exterior surface is selectively coated with a base layer that serves as a primer or foundation. A chelator is covalently attached to either an optional spacer material or directly to the base layer. The top radioisotope layer is applied just prior to use. Eury, col. 4, line 1- col. 5, line 12. Thus, the radioisotope is applied to a chelator. A chelator is a chemical compound in the form of a heterocyclic ring, containing a metal ion attached by coordinate bonds to at least two nonmetal ions. Therefore, Eury does not disclose a nuclide

that is a chemically bound constituent of a polymer chain of the integral source material as recited in the present application. In addition, Eury does not disclose a nuclide that is activatable by exposure to radiation, as conceded by the Action (page 4, third paragraph).

Park discloses a radioactive stent and a post-irradiation method including the steps of "adhering the sleeve which contains stable isotopes onto a non-radioactive stent and then irradiating it with neutrons in a nuclear reactor." Park, col. 6, lines 29-39. Park does not disclose a nuclide that is a chemically bound constituent of a polymer chain, as claimed in the present invention. In contrast, Park describes a process in which the "radionuclide is evenly mixed with the ... carrier material evenly and dried to be dispersed and fixed within the carrier polymer..." Park, col. 6, lines 23-28.

Suthanthiran discloses a pellet for a radioactive seed. Suthanthiran discusses that the "radioactive material ... will be both chemically and physically bound to the radioactive-absorbing material." Sunthanthiran, col. 4, lines 32-34. However, Suthanthiran does not disclose a nuclide that is a chemically bound constituent of a polymer chain. Suthanthiran states that "[i]t is believed that the chain length of the polymeric binder materials should be long enough to bind the material to the substrate, but also permit the radioactive material to be absorbed physically therein." Suthanthiran, col. 4, lines 24-28. In addition, Suthanthiran has no discussion regarding a nuclide that is activatable by exposure to radiation, as conceded by the Action (page 4, third paragraph).

Therefore, none of the references disclose a nuclide that is both activatable by exposure to radiation and a chemically bound constituent of a polymer chain of the integral source material as claimed in the present invention. A *prima facie* case of anticipation under 35 U.S.C § 102 has not been made because no prior art reference teaches every element of the claim.

Furthermore, Applicant submits that none of the claimed devices are taught or suggested in the cited references. Claim 1 as amended recites, "the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy dispersive fluorescence analysis." Park and Eury disclose a radioactive stent and Suthanthiran discloses a pellet for a radioactive seed that is suitable for use in medical radiological treatments.

The radioactive stents and pellets disclosed by Park, Eury, and Suthanthiran are each designed for medical use to irradiate a relatively small, localized area. For example, Suthanthiran states that "[t]o effectively treat the patient, it is desirable to have such a source which will irradiate the diseased tissue while minimizing damage to nearby healthy tissue." Suthanthiran, col. 1, lines 13-17. Therefore, the internal pellets and encapsulated seeds disclosed in Suthanthiran are small, typically having dimensions of less than 15mm. Suthanthiran, col. 6, lines 48-68. Eury discusses the treatment of a variety of conditions by local irradiation of tissue and a stent configured to administer such localized treatment. Eury, col. 1, lines 9-11, and col. 5, lines 19-20. Park discusses the desirability to use a stent to irradiate lesion sites "evenly and closely." Park, col. 10, lines 22-25.

Although embodiments of Applicant's invention can be configured to administer localized radiation such as in medical applications, other embodiments of Applicant's invention include test objects, large area sources such as rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds, and excitation sources for energy dispersive fluorescence analysis. Such devices are not taught or suggested by Suthanthiran, Eury, or Park.

Because none of the references disclose the claimed devices, a *prima facie* case of anticipation under 35 U.S.C § 102 has not been made because no prior art reference teaches every element of the claim. Applicant requests that such rejection be withdrawn.

V. Claim rejections under § 103.

In order to establish a *prima facie* case of obviousness under § 103, the prior art reference or references must teach or suggest all the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success. *See* M.P.E.P § 2143. Applicant respectfully contends that the references cited by the Examiner do not teach or suggest all the claim limitations, and furthermore, there is no motivation or expectation of success to combine the teaching of the references.

As discussed above, the cited references do not teach or suggest a nuclide that is a chemically bound constituent of a polymer chain of the integral source material. As

discussed above, Park describes a radionuclide that is dispersed and fixed within the carrier polymer. Park, col. 6, lines 23-28. Eury describes a radioisotope that is applied to a chelator, i.e., a chemical compound in the form of a heterocyclic ring. Eury, col. 4, line 1- col. 5, line 12. Suthanthiran is the only reference that mentions any type of chemical binding, but Suthanthiran does not disclose a nuclide that is a chemically bound constituent of a polymer chain.

Even assuming for the sake of argument that Suthanthiran discloses a nuclide that is a chemically bound constituent of a polymer chain, none of the references disclose a nuclide that is both activatable by exposure to radiation and a chemically bound constituent of a polymer chain. The Action states that it is "well known in the art of radioactive seeds that, that starting with an activatable isotope provides increased safety and preparation as shown by Park and Good." The Action, page 4, paragraph 3. Applicant submits that it is not well known to use an activatable isotope that activated after being formed as a chemically bound constituent of the polymer chain.

Good merely states that one object of the invention of Good is "to provide a novel method for incorporation of a nonradioactive elemental isotope into a seed during manufacture of a seed that will later form the desired radioactive isotope when the finished seed is bobarded with neutrons." Good, col. 3, lines 4-10. Chemical binding to a polymer or polymer chain prior to forming the desired radioactive isotope is not disclosed. Park discloses irradiating a non-radioactive stent with neutrons, where the radionuclide is "dried to be dispersed and fixed within the carrier polymer." Park, col. 6, lines 23-39. Therefore, Park teaches away from the claimed invention because Park describes a physical fixation of the radionuclide within a carrier polymer. In contrast, the present invention claims a nuclide that is both activatable by exposure to radiation and a chemically bound constituent of a polymer chain.

Furthermore, as discussed above, none of the references teach or suggest the claimed devices and there is no motivation presented to modify the references to arrive at Applicant's claimed invention. Park and Eury disclose a radioactive stent and Suthanthiran discloses a pellet for a radioactive seed that is suitable for use in medical radiological treatments. Such devices are configured for specific uses, in particular, to administer a controlled dose of radiation by a medical device to a localized area. Although embodiments of Applicant's

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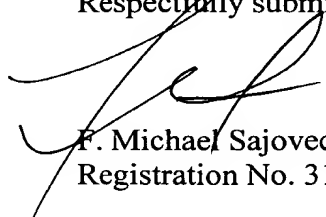
invention can be used to administer a controlled dose of radiation to a localized area, the present invention recites "the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy dispersive fluorescence analysis." Such devices are configured for applications that may be unrelated to the stents and pellets disclosed by Park, Eury, and Suthanthiran, and no motivation exists to modify the references to arrive at Applicant's claimed invention.

For the reasons discussed above, the cited references do not teach or suggest all the claim limitations, and there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Therefore, Applicant requests that the rejections under 35 U.S.C. § 103 be withdrawn.

VI. Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance and respectfully requests same. The Examiner is requested to contact the undersigned to resolve any remaining issues.

Respectfully submitted,

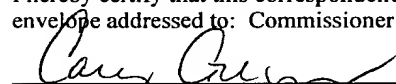


F. Michael Sajovec
Registration No. 31,793

Myers Bigel Sibley & Sajovec, P.A.
P.O. Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on October 22, 2002.



Carey Gregory
Date of Signature: October 22, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The following is an addendum to the concurrently filed Amendment in response to the Official Action dated April 22, 2002 in the above-referenced application. This addendum includes a marked-up version of the changes made to the specification and claims by the present Amendment.

In the claims:

Please amend the claims as follows:

1. (Amended) An integral source material having at least one nuclide that is activatable by exposure to radiation, the nuclide is a chemically bound constituent of a polymer chain of the integral source material, wherein the integral source material is configured before activation to provide a device wherein the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy-dispersive fluorescence analysis.

Please cancel Claim 2.